K051344

ATTACHMENT B

Ultimate Concepts Inc.

5056 Crimson Patch Way
Riverton, Utah 84065
Phone 800-682-3241 or 801-566-3214

AUG 18 2005

SUMMARY

Submitter's name:	Ultimate Concepts, Inc.
Address:	5056 Crimson Patch Way Riverton, Utah 84065
Phone:	800-632-3241
Fax number:	801-566-7152
Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821

Date the summary was prepared: July 18, 2005

Trade Name:	Colonic and Enema Nozzle
Common/Usual Name:	Colonic and Enema Nozzle
Classification Name:	Colonic Irrigation System, Enema Kit

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

This Colonic Nozzle is equivalent to Ultimate Professional Continuous Flow colonic System, K033149.

Description of the device:

This Colonic nozzle is made of medical grade tubing, has an opening on one end. The other end is sealed with a small hole in the middle and has two holes on the sides at the same end.

Indications:

The Colonic Nozzle is an attachment to colon cleansing systems.

Technological characteristics of our device compared to the predicate device, Ultimate Professional Continuous Flow colonic System, K033149, are exactly the same except for material used and the addition of a hole at one end. The new material is still medical grade and therefore equivalent. The hole at the end is equivalent to the design of the Jimmy John nozzle, K973256.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2005

Ultimate Concepts, Inc.
c/o Ms. Grace Holland
Regulatory Consultant
Regulatory Specialists, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

Re: K051344
Trade/Device Name: Colonic Nozzle
Regulation Number: 21 CFR §876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: KPL
Dated: July 18, 2005
Received: July 21, 2005

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT A

Indications for Use Statement

510(k) Number (if known): K051344

Device Name: Colonic Nozzle

Indications For Use:

The Colonic Nozzle is to be used as an attachment to gravity fed colonic systems for cleansing when medically indicated such as before radiological or endoscopic examination.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801Subpart D) (21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051344